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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,287	05/15/2001	Arthur C. Coffey	7175-67882	1909

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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,287

Applicant(s)

COFFEY, ARTHUR C.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2, 6-9,14-18,27,28,30-37 and 39-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-9,14-18,27,28,30-37 and 39-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3-15-2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt of RCE & IDS dated 3-15-04; remarks and declaration dated 3-18-04 is acknowledged.

Claims 1, 2, 6- 9, 14-18, 27, 28, 30-37 and 39-45 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-15-04 has been entered.

Claim Rejections - 35 USC § 103

Claims 1, 2, 8, 9, 14-18, 27, 28, 30-37 and 39-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,645,081 to Argenta and US 4,970,298 to Silver et al (Silver) in view of US 6,695,823 to Lina et al (Lina).

Instant claims are directed to a wound care bandage comprising a collagen matrix, a cover to seal the wound that is adapted for communication with a vacuum source, and a structure for placement between the collagen matrix and the wound cover. The collagen matrix in the instant claims is placed on the wound surface and integrates upon placement into the wound.

Argenta teaches a method of treating tissue damage in burns and wounds (abstract, col. 1, lines 55-65). The apparatus of Argenta comprises a vacuum means for creating a negative pressure on the area of tissue surrounding the wound, sealing means operatively associated with the vacuum means to maintain negative pressure on the wound and a screen means to prevent

overgrowth of tissue in the wound area. The screen means comprises a section of open-cell foam, which is porous, configured to be placed over a wound, into which is inserted a flexible tube for attachment to a suction pump. The sealing means comprises a polymeric sheet above the foam section and tubing such that it is adhered to the skin surrounding the wound (col. 2, lines 15-28). Argenta teaches that the screen means is a semi-rigid structure and is directly connected to the vacuum source (col. 4, lines 29-60) and the screen means reads on the instant structure placed between the collagen matrix and the cover. Argenta teaches application of pressure in cycles in alternate periods of application and non-application (col. 3, lines 9-18). Further, Argenta teaches that the method of applying negative pressure enables increased blood flow into the wound area, reduces the bacterial infection in the area and thus enhances wound healing and (col. 3, lines 29-46), which is also claimed in the instant method claims.

Argenta lacks a collagen layer in contact with the wound, as in the instant claims.

Silver teaches a biodegradable matrix of collagen that is porous in nature and having a morphology that enhances the healing of a wound (abstract, col. 6, lines 10-29). Silver teaches that the collagen matrix can be formed into a sheet or a sponge having desired pore size (col. 4, lines 35-40). Silver teaches that the collagen based matrix has a swelling ratio of 2.5 to 5, which is required when it comes in contact with open wounds and can be used for placing in direct contact with the wound (col. 6, lines 30-46). Silver further teaches preparing collagen fibers that forms channels, which connect interior sponge to the pores (col. 8, lines 56-68). Silver teaches porous collagen for providing effective wound healing, but does not teach a wound dressing system with provided with a vacuum source as claimed.

Lina teaches a wound therapy device comprising a housing containing a vacuum pump and a chamber for holding a disposable fluid collection canister. The canister connects to an outlet with the vacuum pump at and at an inlet with a porous wound pad, which is placed over the wound. Upon activation of vacuum pump, wound fluid is drawn into the canister due to negative pressure (abstract, figures 10-16, col. 6, lines 1-14). Lina refers to the teachings of WO 93/09727, which claims priority to the patent of Argenta (cited in this rejection) (see col. 1). Lina teaches that the development over the teachings of Argenta comprise that the pad is a biodegradable material having sufficient porosity, enabling the draining of the wound fluids. Further, Lina teaches that the pad made of polyurethane or polyether foam is porous and that the wound fluids are communicated through the inlet into the canister via the pad (col. 5, lines 40-45).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add porous collagen matrix of Silver, having a sufficient pore size, in the vacuum assisted therapy for wound healing of Argenta because Lina suggests that employing a biodegradable foam pad having pores of appropriate size on the wound and connect to a vacuum pump so as to drain the wound fluids without the problems of contamination and that a biocompatible pad is both compatible with vacuum, negative air flow and with healing tissue. In this regard, Silver teaches that collagen matrix is biodegradable, the biodegradability of which can be controlled, it can be prepared in the form of a sheet or a sponge, where the pore size of the sponge can be adjusted depending on the requirement and that the porous collagen has a swelling capacity that meets needs of absorbing the fluids from wounds. Accordingly, one of an ordinary skill in the art at the time of the instant invention would have incorporated a porous collagen in

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the vacuum assisted wound device of Argenta with an expectation to withdraw the wound exudates (including blood) in to collagen due its swelling capacity and porosity and that collagen integrates in to the wound over a period of time, owing to its biodegradability. Further, while neither reference teach the specific ring shaped structure of claims 14 and 32, Argenta teaches the same porous material and for the same purpose i.e., absorb exudates. Therefore, using an appropriate shaped structure of the pad, without altering the recognized function would have been within the scope of a skilled artisan.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,645,081 to Argenta and US 4,970,298 to Silver et al (Silver) in view of US 6,695,823 to Lina et al (Lina), as applied to claims 1, 2, 8, 9, 14-18, 27, 28, 30-37 and 39-45 above, and further in view of US 6,440,427 to Wadstrom.

The wound dressings of Argenta, Silver and Lina, discussed above, do not contain instant fibrin glue for holding collagen matrix.

Wadstrom teaches tissue treatment composition comprising fibrin or fibrinogen, and biodegradable polymers for wound healing or slow-release drug formulations etc (col. 1, lines 12-15). Wadstrom teaches fibrin is a known biological adhesive and is mixture of fibrin and thrombin that forms a coagulum (col. 1, lines 23-30). Wadstrom teaches fibrin sealants act in several ways, in hemostasis, glueing and wound healing. Further, Wadstrom teaches that fibrin sealants are used in a number of fields, especially for wound healing and prevention of adhesion of adjacent tissues (col. 3, lines 37-48).

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It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the fibrin sealant of Wadstrom in the wound dressing of Argenta, containing collagen of Silver because Wadstrom suggests that fibrin glue, due to its adhesive properties, is capable of atraumatically connecting tissues by forming a strong joint between them and adapts uneven wound surfaces, promotes the growth of fibroblasts, which in combination with efficient hemostasis and adhesion between the wound surfaces provides for an improved healing process. Further, Wadstrom teaches that the fibrin glueing effect is increased by fibronectin binding to exposed collagen (col. 1, lines 57 through col. 2, lines 15). Accordingly, one of an ordinary skill in the art would have expected to increase the homeostasis and fibroblast growth at the wound-healing site, by placing fibrin glue close to the collagen layer in the wound dressing of Argenta.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 6-9, 14-18, 27, 28, 30-37 and 39-45 have been considered but are moot in view of the new ground(s) of rejection.

Applicants' Declaration dated 3-18-04, under 37 CFR 1.132, has been considered but has not been found persuasive. Applicant states that at the time of the instant invention, it was required that the matrix would adhere to the wound surface to provide healing and it was not believed that use of a vacuum system with a collagen bandage would be a good idea since the vacuum system would lift off the collagen matrix from the wound, thus drying the collagen too quickly. However, the argument is not persuasive because the above new grounds of rejection applied to instant claims is based on the teaching of a porous collagen, in which the pore size can be adjusted and that the fibers of collagen form channels connecting the interior to the exterior,

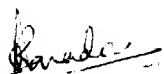
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enabling absorption of fluids. Further, Lina suggests that that the porous pad that is used for draining wound fluids is biocompatible and have sufficient pore size. Thus, the collagen matrix having an adjustable porosity taught by Silver, meets the requirements of Lina, for successfully draining wound fluids, using a vacuum system that creates a negative pressure. Further, the removal of collagen or the adherence of the collagen to the wound depends on the pressure applied for drawing fluids and also on the type of collagen used, such that it can withstand the pressure applied. Applicants have not shown any difference between the collagen of prior art and that used and hence the examiner maintains the rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lakshmi S Channavajjala
Examiner
Art Unit 1615
June 23, 2004